

Serial No.: 10/712,260
Atty. Docket No.: P69290US0

REMARKS

By this Amendment, Applicants have amended claims 1, 7, 8 and 24. Claims 1-21 and 24 are pending in the application. Claims 11-21 have been withdrawn.

The Examiner rejected claims 7, 8 and 24 under 35 U.S.C. 112, second paragraph, as being indefinite. By this Amendment, Applicants have amended claim 24 to depend from claim 3 which provides proper antecedent basis therefor. Applicants have also deleted the trademark and trade names previously set forth in claims 7 and 8 and have inserted in place thereof a generic description of the materials or products represented by these trademarks and trade names. A similar description has been added to the specification. No new matter has been introduced as the materials represented by these trademarks and trade names are known to persons of ordinary skill in the art, as evidenced by the representative web pages which are attached hereto for the Examiner's convenience.

The Examiner rejected claims 1-4 and 24 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,510,065 to McFarlane. Also under 35 U.S.C. 102(b), the Examiner rejected claims 1, 2, 6-8 and 10 as being anticipated by WO 90/00960 to Glocker et al. ("Glocker"), and rejected claims 1, 2, 7 and 8 as

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being anticipated by U.S. Patent No. 5,032,343 to Jeffs or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Jeffs. Claims 5-10 were also rejected under 35 U.S.C. 103(a) as being unpatentable over any one of McFarlane, Glocker or Jeffs and further in view of U.S. Patent No. 6,630,086 to Goral et al.

As set forth in amended claim 1, the present invention is directed to a method for one-piece injection moulding of a soft needle catheter having a hub and a tube-shaped flexible part, *both of which parts are formed through the one-piece injection moulding method*. The method includes the steps of feeding a molten polymer into a mould having a core which is used to form an interior of the catheter. The mould and the core together define a hub cavity and a tube-shaped cavity having a cylindrical part for forming the hub and the tube-shaped flexible part, respectively. This step of feeding includes using a core having a cone-shaped part that extends from the hub cavity into the tube-shaped cavity to create *within the tube-shaped cavity a cone-shaped part* between the cylindrical part and the hub cavity. The cone-shaped part facilitates removal of the core when the polymer has been sufficiently cured for the core to be removed. The resulting soft needle catheter formed from the above-described one-step injection moulding method is then removed from the mould when the polymer has

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been sufficiently cured to be removed. This use of a cone-shaped part in the tube-shaped cavity to ease release of the core during catheter production is not shown or suggested by the prior art.

McFarlane discloses a method of in-line injection moulding using a mould cavity portion 20 having a cylindrical cavity 24 around the core pin 22 and a widened upper area around the core pin head 23 representing the hub cavity. The cylindrical cavity 24 may be said to correspond with the tube-shaped part 4 of the present invention. However, unlike the claimed invention, this cylindrical cavity 24 has a constant inner diameter in the portion extending from the hub. There is nothing in McFarlane to suggest any motivation to modify this cylindrical part adjacent the hub to have a diameter that decreases lengthwise from the hub to a distal cylindrical part to form a cone-shaped part. Therefore, claim 1 is patentable over McFarlane.

Glocker discloses a method for one-piece injection moulding of a soft needle catheter that includes the steps of feeding a molten polymer into a mould having a core which together define a cavity composed of a hub cavity 12, 13 and a tube-shaped cavity 11 (see Figure 2 of Glocker). The hub cavity 12, 13 has a cone-shaped part as shown in Figure 2, but this cone-shaped part *does not extend into the tube-shaped cavity 11*. Therefore, Glocker

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does not disclose using a core having a cone-shaped part that extends from the hub cavity into the tube-shaped cavity to create a cone-shaped part *within the tube-shaped cavity*, as claimed by the present invention.

Furthermore, Glocker does not suggest the claimed method because Glocker solves the mould-removal problems associated with forming thin-walled tubes by injection moulding in an entirely different way than that claimed by the present invention. Specifically, according to Glocker a problem with the production of hollow cylindrical tubes having a length of 10-150 mm by injection moulding lies in that for thin-walled parts, i.e., wall thicknesses of less than 0.3 mm, the core of the mould holding the interior of the hollow cylinder open has to be precisely centered since only slight deviations from the coaxial position lead to irregular tube wall thicknesses and irregular material flow within the mould (see the third full paragraph on page 5 of Glocker). Such irregularities can be made worse by sticking of the tube material during mould removal. This problem is solved in Glocker by using a sleeve which is movably located in the annular space between the mould and the core to achieve the centering and to assist in removal of the core after curing. Obviously, this sleeve movement must be effected with great precision.

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The present invention, by contrast, provides a method for forming thin-walled tubes without the need for a centering sleeve. Instead, the claimed invention uses a core having a cone-shaped part that forms at least part of the interior of the hub and which extends into the interior of the tube-shaped part so as to form an interior of the flexible tube-shaped part that is at least partially cone-shaped. This tapered portion facilitates wrinkle-free removal of the thin-walled catheter from the mould and makes the production process cheaper and simpler (see the specification on page 3, lines 11-16). There is nothing in Glocker that would suggest that the problems encountered during mould removal in the process of forming thin-walled tubes can be solved in this way. Accordingly, claim 1 is patentable over Glocker.

Jeffs is directed to a method of producing medical micro pipette tips in which the distal portion of the tip or extension 64 is flexible so as to be able to access hard to reach places while preventing occlusion of the central passage 68 (see the abstract and column 5, lines 7-8). The cone-shaped part 24 of the pipette 20, 60 remote from the tip, however, has to be "of such a nature that it may not be materially bent, flexed or curvilinearly displaced" (see column 4, lines 18-27 and lines 55-57). The

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resulting structure is not analogous to the claimed invention no matter how Jeffs is interpreted.

First, if the cone-shaped part 24 of the micro pipette 60 is to be equated with the hub 3 of the presently claimed invention, then the tube-shaped flexible part 64 of the micro pipette tip does not have a cone-shaped part, but is entirely cylindrical. In this case, claim 1 is patentable over Jeffs.

Alternatively, if only the upper part of the cone-shaped part 24 of the micro pipette 60, i.e., that part stretching from the upper end adjacent reference numeral 30 down to the shoulder 34 (see Figure 6 of Jeffs), is to be compared with the hub 3 of the presently claimed invention, then the tube-shaped part which stretches from the shoulder 34 to the end 66 cannot be described in its totality as being flexible. Rather, as defined at column 5, line 4, the material from the shoulder 34 to the site 62, namely the portion 24, is provided with substantial rigidity. In this case too, claim 1 is patentable over Jeffs in that claim 1 sets forth that the tube-shaped part is flexible.

Finally, the micro pipette product of Jeffs differs significantly in use from the soft needle catheter of the presently claimed invention. The micro pipette needs to have a dimensionally stable upper part which can be fastened to a metering device and

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thereafter used to collect and dispense fluids. The soft needle catheter, on the other hand, is partly inserted intravenously or subcutaneously with an introducer needle. Therefore, it is important that the outer surface of the tube-shaped flexible part be smooth and comfortable. In addition, the fact that the tube-shaped flexible part which is positioned subcutaneously can be as short as 7 mm long makes special demands upon the production method.

For at least the foregoing reasons, claim 1 as amended is patentable over the prior art. Claims 2-10 and 24 are also in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter contained therein.

With this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance.

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Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

JACOBSON HOLMAN PLLC

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Attachments

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Ecdel 9967 - Eastman Chemical Company - Thermoplastic Elastomer

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Ecdel 9967 by Eastman Chemical Company is a TPE (Thermoplastic Elastomer) plastic material.

General Information

Product Description

Ecdel elastomers are copolyester ethers (COPE). They offer the clarity, toughness, and chemical resistance needed in a variety of flexible packaging including medical applications. Ecdel elastomer 9967 may be injection molded or extruded. In addition, it may be extrusion blow molded or processed into tubing. Ecdel elastomers may be extrusion blow molded directly into bags or extruded into film for later fabrication into bags.

General

| | |
|--------------------------|--|
| Material Status | o Commercial: Active |
| Availability | o Africa o Asia o Australia o Europe o Latin America o Middle East o North America o Pacific Rim o South America |
| Test Standards Available | o ASTM |
| Features | o Chemical Resistance, Good o Clarity, Medium o Toughness, Good |
| Uses | o Bags o Film o Medical Applications o Packaging o Packaging, Pharmaceutical o Tubing |
| Forms | o Pellets |
| Processing Method | o Extrusion o Extrusion Blow Molding o Extrusion, Film o Injection Molding |

Other Information for this Plastic

How to Access the Full Plastic Material Data Sheet for this Grade

The information presented on this page is just a summary for this plastic material. The full plastic data sheet containing additional general information, technical properties, and processing specifications is available from IDES. [Click here to register for free access.](#) After registering, you'll have immediate access to more than 60,000 full plastic material data sheets from 500 global resin suppliers.

Features (Alternate Representations)

Medium Clarity, Good Toughness, Tough, Good Chemical Resistance, Chemical Resistant.

Uses (Alternate Representations)

Tubing, Tube, Pharmaceutical Packaging.

Spelling Variations

The terms listed below may be used to identify this product. They are provided to assist you in finding pertinent documentation from supplier and non-supplier sources. They are included for informational purposes only, and are typically NOT representations that have been specified by the supplier. Possible spelling variations for terms related to this product are:

Ecdel9967, Ecdel , Thermoplastic Elastomer, ThermoplasticElastomer, TPE, Eastman



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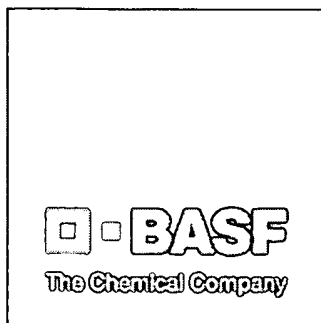
and urges that upon final plastic material selection, data points are validated with the resin manufacturer.

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Lupolen and Hostalene

Lupolen and Hostalene are the trade names of BASSELL Polyolefins CO., for the range medium- and low-density polyethylenes. Lupolen and Hostalene are utilized for wide v applications, such as film, extrusion blow, steel pipe coating, extrusion pipe, injection so on.

In Japan we deal with product grades that cover many processing techniques and ap focusing on ones for blow molding (e.g. PFT (Plastics Fuel Tanks, IBC, chemical dru extrusion molding (e.g. coated steel pipes, plastics pipes). Especially for PFT applica Lupolen 4261AG to many PFT makers along with the same quality of product produc production sites: Germany, U.S.A and Korea, using the same catalyst and production well as the same quality management system.

The following are typical Lupolen and Hostalene grades applied for PFT, IBC and Che

Lupolen: PFT Application (4261AG, 4261AQ444, 4261AQ404)

Lupolen: IBC & Chemical Drum Application (4261AGUV60005, 5261ZHI)

Hostalene: Electrostatic Grade (Fuel Tube) (GM9350C Black)

Product list ([PDF](#))

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PELLETHANE Thermoplastic Polyurethane Elastomers

PELLETHANE™ thermoplastic polyurethane elastomers range from hard to soft and can be formed by injection molding to extrusion to blow molding. These elastomers offer a combination of properties rarely found in other plastics. Whether you need clarity and abrasion resistance, tensile strength and chemical resistance, or PELLETHANE elastomers are an excellent choice.

PELLETHANE elastomers offer several advantages over most thermoset materials. For example, they achieve faster cycle times than most thermosets, and could be more cost-effective overall.

For automotive applications, PELLETHANE elastomers offer a combination of performance and temperature impact resistance. Parts fabricated from PELLETHANE elastomers can be painted with acrylic enamels or water-based elastomeric paints.

Action Legend([Close](#))[T](#) Technical Datasheet, [M](#) Material Safety DatasheetPage 1 2 3 4 5
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| Action | Product | Generic Name | Density (g/cm ³) |
|-------------------------------------|-----------------------|--|---------------------------------|
| T M | PELLETHANE™ 2101-85A | Thermoplastic Polyurethane Elastomer (Polyester) | 1.13 (ASTM D |
| T M | PELLETHANE™ 2102-55D | Thermoplastic Polyurethane Elastomer (Polyester) | 1.21 (ASTM D |
| T M | PELLETHANE™ 2102-65D | Thermoplastic Polyurethane Elastomer (Polyester) | 1.22 (ASTM D |
| T M | PELLETHANE™ 2102-75A | Thermoplastic Polyurethane Elastomer (Polyester) | 1.17 (ASTM D |
| T M | PELLETHANE™ 2102-80A | Thermoplastic Polyurethane Elastomer (Polyester) | 1.18 (ASTM D |
| T M | PELLETHANE™ 2102-85A | Thermoplastic Polyurethane Elastomer (Polyester) | 1.18 (ASTM D |
| T M | PELLETHANE™ 2102-85AH | Thermoplastic Polyurethane Elastomer (Polyester) | |
| T M | PELLETHANE™ 2102-90A | Thermoplastic Polyurethane Elastomer (Polyester) | 1.20 (ASTM D |
| T M | PELLETHANE™ 2102-90AE | Thermoplastic Polyurethane Elastomer (Polyester) | 1.20 (ASTM D |
| T M | PELLETHANE™ 2102-90AR | Thermoplastic Polyurethane Elastomer (Polyester) | 1.20 (ASTM D |
| Action | Product | Generic Name | Density (g/cm ³) |

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Tecothane® TT-2075-B40 - Noveon, Inc. - Thermoplastic Polyurethane Elastomer (Polyether)
Please [login](#) or [register](#) to view the full datasheet.

Tecothane TT-2075-B40 by Noveon, Inc. is a TPU-Polyether (Thermoplastic Polyurethane Elastomer (Polyether)) plastic material with filler: Barium sulfate, 40 %.

General Information
General

| | |
|--------------------------|--|
| Material Status | o Commercial: Active |
| Availability | o North America |
| Test Standards Available | o ASTM |
| Filler/Reinforcement | o Barium sulfate, 40 % Filler by Weight |
| Features | o Aromatic o Processability, Good o Radiopaque o Solvent Resistant o Sterilizable, Ethylene Oxide o Sterilizable, Radiation |
| Uses | o Medical Applications |
| Appearance | o Colors Available |
| Forms | o Pellets |
| Processing Method | o Blow Molding o Extrusion o Injection Molding |

Other Information for this Plastic
How to Access the Full Plastic Material Data Sheet for this Grade

The information presented on this page is just a summary for this plastic material. The full plastic data sheet containing additional general information, technical properties, and processing specifications is available from IDES. [Click here to register for free access.](#) After registering, you'll have immediate access to more than 60,000 full plastic material data sheets from 500 global resin suppliers.

Features (Alternate Representations)

Good Processability, Easy Processing, Ethylene Oxide Sterilizable, Radiation Sterilizable.

Spelling Variations

The terms listed below may be used to identify this product. They are provided to assist you in finding pertinent documentation from supplier and non-supplier sources. They are included for informational purposes only, and are typically NOT representations that have been specified by the supplier. Possible spelling variations for terms related to this product are:

Tecothane TT2075B40, TecothaneTT2075B40, Tecothane® , Tecothane, TT2075B40, TT:2075:B40, TT/2075/B40, TT+2075+B40, TT_2075_B40, TT 2075 B40, TT-2075-B 40, TT-2075-B40, 40TT-2075-B, TT, Thermoplastic Polyurethane Elastomer (Polyether), Thermoplastic Polyurethane Elastomer Polyether, ThermoplasticPolyurethaneElastomerPolyether, Thermoplastic Polyurethane Elastomer, TPU-Polyether, TPUPolyether, TPU:Polyether, TPU/Polyether, TPU+Polyether, TPU_Polyether, TPU Polyether, Thermoplastic Polyurethane, ThermoplasticPolyurethane, TPU, Noveon



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Selection & Specification Data

| | |
|----------------------------------|--|
| Generic Type | Aliphatic-Acrylic-Polyester-Polyurethane |
| Description | High build, low sheen finish that has excellent resistance to corrosion, chemicals and abrasion. Suitable for application over a number of Carboline primers and intermediates, this material provides very good weathering performance in a broad range of colors. |
| Features | <ul style="list-style-type: none"> Outstanding performance properties in both mild and aggressive environments High build; suitable for many two-coat systems Suitable for application direct to inorganic zincs Application by spray, brush or roller VOC compliant to current AIM regulations |
| Color * | Refer to Carboline Color Guide. Certain colors may require multiple coats to hide. |
| Finish | Satin |
| Primers | Refer to <i>Substrates & Surface Preparation</i> |
| Topcoats | Carbothane® Clear Coat when required. |
| Dry Film Thickness | 3.0-5.0 mils (75-125 microns) per coat. Dry film thickness in excess of 7 mils (175 microns) per coat is not recommended. |
| Solids Content | By Volume: 57% ± 2% |
| Theoretical Coverage Rate | 914 mil ft ² (22.8 m ² /l at 25 microns) 228 ft ² at 4 mils (5.7 m ² /l at 100 microns) Allow for loss in mixing and application. |
| VOC Values | As supplied: 3.2 lbs./gal (383 g/l) Thinned: 11 oz/gal w/ #25: 3.5 lbs./gal (420 g/l) 18 oz/gal w/ #25: 3.7 lbs./gal (449 g/l) These are nominal values and may vary slightly with color. |
| Dry Temp. Resistance | Continuous: 200°F (93°C) Non-Continuous: 250°F (121°C) Discoloration and loss of gloss is observed above 200°F (93°C). |

* The alignment of aluminum flakes in aluminum-filled finishes is very dependent on application conditions and techniques. Care must be taken to keep conditions as constant as possible to reduce variations in final appearance. It is also advisable to work from a single batch of material since variations can occur from batch to batch. For more information consult Carboline Technical Service Department.

Substrates & Surface Preparation

| | |
|------------------------------------|--|
| General | Surfaces must be clean and dry. Employ adequate methods to remove dirt, dust, oil and all other contaminants that could interfere with adhesion of the coating. Refer to the specific primer's Product Data Sheet for detailed requirements of the specified primer. |
| Steel | SSPC-SP6 with a 1.5-2.5 mil (37.5-62.5 micron) surface profile for maximum protection. SSPC-SP2 or SP3 as minimum requirement. Prime with specific Carboline primers as recommended by your Carboline sales representative. |
| Galvanized Steel | Prime with specific Carboline primers as recommended by your Carboline Sales Representative. Refer to the specific primer's Product Data Sheet for substrate preparation requirements. |
| Aluminum | SSPC-SP1 and prime with appropriate Carboline primer as recommended by your Carboline sales representative. |
| Previously Painted Surfaces | Lightly sand or abrade to roughen and degloss the surface. Existing paint must attain a minimum 3B rating in accordance with ASTM D3359 "X-Scribe" adhesion test. Prime with specific Carboline primers as recommended by your Carboline sales representative. |

Performance Data

| Test Method | System | Results | Report # |
|---|--|--|----------|
| ASTM D4213 Scrub Resistance | 1 ct. 133 HB | .0027 microliters erosion rate after 100 cycles with abrasive scrub medium. | 03403 |
| ASTM G26 Weatherometer | Blasted Steel 1 ct. IOZ 1 ct. 133 HB | No blistering, rusting or cracking after 3500 hours. | 01982 |
| ASTM G53 QUV (2500 hours w/ UVA 340 bulb) | Blasted Steel 1 ct. Epoxy 1 ct. 133 HB | Color change less than 2 McAdam units; no blistering, rusting, cracking or chalking. | 03394 |
| ASTM B117 Salt Fog | Blasted Steel 1 ct. OZ 1 ct. 133 HB | No rusting, or blistering on plane or scribe 4,000 hours | 02585 |
| ASTM B117 Salt Fog | Blasted Steel 1 ct. IOZ 1 ct. 133 HB | No rusting, or blistering on plane or scribe 2,000 hours | 02585 |
| ASTM D5894 QUV A Prohesion | 1 ct. 133 HB | No effect on plane area and 78% gloss retention after 1008 hours of wet/dry salt fog cycle | 03274 |
| ASTM D4585 Humidity | Blasted Steel 1 ct. IOZ 1 ct. 133 HB | No rusting or blistering after 3000 hours. | 02585 |
| Graffiti Resistance | Blasted Steel 1 ct. Epoxy 1 ct. 133 HB | All markings and stains removed by solvent after exposure to: shoe polish, Sharpie marker, crayon, lipstick, spray cans of acrylic, alkyd and epoxy. | 03395 |
| ASTM D1735 Water Fog | Blasted Steel 1 ct. Epoxy 1 ct. 133 HB | No rusting or blistering after 8600 hours. | 02061 |

Test reports and additional data available upon written request.

April 2003 replaces December 2002

0840

To the best of our knowledge the technical data contained herein is true and accurate on the date of publication and is subject to change without prior notice. User must contact Carboline Company to verify correctness before specifying or ordering. No guarantee of accuracy is given or implied. We guarantee our products to conform to Carboline quality control. We assume no responsibility for coverage, performance or injuries resulting from use. Liability, if any, is limited to replacement of products. NO OTHER WARRANTY OR GUARANTEE OF ANY KIND IS MADE BY CARBOLINE, EXPRESS OR IMPLIED, STATUTORY, BY OPERATION OF LAW, OR OTHERWISE, INCLUDING MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. Carboline® and Carbothane® are registered trademarks of Carboline Company.

Carbothane®133 HB

Application Equipment

Listed below are general equipment guidelines for the application of this product. Job site conditions may require modifications to these guidelines to achieve the desired results.

General Guidelines:

Spray Application (General) This is a high solids coating and may require adjustments in spray techniques. Wet film thickness is easily and quickly achieved. The following spray equipment has been found suitable and is available from manufacturers such as Binks, DeVilbiss and Graco.

Conventional Spray Pressure pot equipped with dual regulators, 3/8" I.D. minimum material hose, .070" I.D. fluid tip and appropriate air cap.

Airless Spray Pump Ratio: 30:1 (min.)*
GPM Output: 3.0 (min.)
Material Hose: 3/8" I.D. (min.)
Tip Size: .013-.015"
Output PSI: 2100-2300
Filter Size: 60 mesh
*Teflon packings are recommended and available from the pump manufacturer.

Brush & Roller (General) Multiple coats may be required to obtain desired appearance, recommended dry film thickness and adequate hiding. Avoid excessive re-brushing or re-rolling. For best results, tie-in within 10 minutes at 75°F (24°C).

Brush Recommended for touch-up only. Use a medium, natural bristle brush.

Roller Use a medium-nap synthetic roller cover with phenolic core.

Mixing & Thinning

Mixing Power mix Part A separately, then combine and power mix. DO NOT MIX PARTIAL KITS.

Ratio 6:1 Ratio (A to B)

Part A: .88 Gal. Kit 5.0 Gal. Kit
1 gal. can (partial filled) 5 gal. can (partial filled)
UC 133: 1 pint 1 gallon can (partial filled)

Thinning Spray: Up to 11 oz/gal (9%) w/ #25.
Roller: Up to 18 oz/gal (14%) w/ #25.
Use of thinners other than those supplied or recommended by Carboline may adversely affect product performance and void product warranty, whether expressed or implied.

Pot Life 4 Hours at 75°F (24°C) and less at higher temperatures. Pot life ends when coating becomes too viscous to use. MOISTURE CONTAMINATION WILL SHORTEN POT LIFE AND CAUSE GELLATION.

Cleanup & Safety

Cleanup Use Thinner #2 or Acetone. In case of spillage, absorb and dispose of in accordance with local applicable regulations.

Safety Read and follow all caution statements on this product data sheet and on the MSDS for this product. Employ normal workmanlike safety precautions. Hypersensitive persons should wear protective clothing, gloves and use protective cream on face, hands and all exposed areas.

Ventilation When used in enclosed areas, thorough air circulation must be used during and after application until the coating is cured. The ventilation system should be capable of preventing the solvent vapor concentration from reaching the lower explosion limit for the solvents used. User should test and monitor exposure levels to insure all personnel are below guidelines. If not sure or if not able to monitor levels, use MSHA/NIOSH approved supplied air respirator.

Cleanup & Safety Cont.

Caution

This product contains flammable solvents. Keep away from sparks and open flames. All electrical equipment and installations should be made and grounded in accordance with the National Electric Code. In areas where explosion hazards exist, workmen should be required to use non-ferrous tools and wear conductive and non-sparking shoes.

Application Conditions

| Condition | Material | Surface | Ambient | Humidity |
|-----------|------------------------|------------------------|------------------------|----------|
| Normal | 65°-85°F (18°-29°C) | 65°-85°F (18°-29°C) | 65°-85°F (18°-29°C) | 35-60% |
| Minimum | 40°F (4°C) | 40°F (4°C) | 40°F (4°C) | 0% |
| Maximum | 100°F (38°C) | 110°F (43°C) | 110°F (43°C) | 90% |

Industry standards are for substrate temperatures to be 5°F (3°C) above the dew point. This product simply requires the substrate temperature to be above the dew point.

Caution: This Product is moisture sensitive in the liquid stage and until cured. Protect from high humidity, dew and direct moisture contact until cured. Application and/or curing in humidities above maximum, or exposure to moisture from rain or dew may result in a loss of gloss and/or microbubbling of the product.

Curing Schedule

| Surface Temp. & 50% Relative Humidity | Dry to Handle | Dry to Recoat | Final Cure |
|---------------------------------------|---------------|---------------|------------|
| 40°F (4°C) | 20 Hours | 20 Hours | 28 Days |
| 50°F (10°C) | 12 Hours | 12 Hours | 14 Days |
| 75°F (24°C) | 5 Hours | 5 Hours | 7 Days |
| 90°F (32°C) | 1 Hour | 1 Hour | 4 Days |

These times are based on a 3.0-5.0 mil (75-125 micron) dry film thickness. Higher film thickness, insufficient ventilation or cooler temperatures will require longer cure times and could result in solvent entrapment and premature failure.

Packaging, Handling & Storage

Shipping Weight (Approximate) .88 Gallon Kit 5 Gallon Kit
11 lbs (5 kg) 64 lbs (29 kg)

Flash Point (Setaflash) Part A: 95°F (35°C)
Part B: 91°F (33°C)

Storage (General) Store Indoors.

Storage Temperature & Humidity 40° -110°F (4°-43°C)
0-90% Relative Humidity

Shelf Life Part A: Min. 36 months at 75°F (24°C)
Part B: Min. 24 months at 75°F (24°C)

***Shelf Life: (actual stated shelf life) when kept at recommended storage conditions and in original unopened containers.**



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An **RPM** Company

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...easily processed by most conventional screws.

Technical Info

C-Flex is a family of patented thermoplastic elastomers (TPE's) which range in hardness from 5 shore A durometer to 95 shore A durometer. C-Flex TPE's are biocompatible polymer blends which meet or exceed the current United States Pharmacopoeia Class VI test requirements. Consolidated Polymer Technologies, Inc. (CPT) the C-Flex patent holder, maintains two Material Master Files with the FDA on C-Flex opaque and clear materials. These master files summarize all the biocompatibility testing completed on C-Flex materials.

C-Flex does not contain latex rubber, polyvinyl chloride, silicone rubber or polyurethane. C-Flex can be processed with most conventional screws. Reciprocating screw injection machines are preferred and can provide lower operating temperatures and more uniform melt characteristics. Cylinder temperatures of 300 – 425F would be typical, injection pressures vary from 300 to 10,000 psi.

(Click Here) to connect to CPT Technical Support Department for additional details on C-Flex for your next project.



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Thermoplastic elastomers (TPE's) combine the processing advantages of thermoplastic with the properties of vulcanized rubber. When heated, TPE's melt and can be formed into complex shapes using standard thermoplastic melt processing equipment. As solids, they are soft, flexible and resilient like rubber and can be decorated, reground, and reprocessed without significant property loss.

C-Flex Property Documentation:

- [Technical Information Sheet, Opaque Formulations](#) (PDF File)
- [Technical Information Sheet, Clear Formulations](#) (PDF File)

To learn more about C-Flex ([click here](#)). We welcome the opportunity to learn more about your application - and to help you understand how C-Flex might be the right solution.